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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,092	04/15/2004	T. Douglas Mast	END5313USNP	7164

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EXAMINER

TOY, ALEX B

ART UNIT	PAPER NUMBER
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3739

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/825,092

Applicant(s)

MAST ET AL.

Examiner

Alex B. Toy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-13 and 15-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-13 and 15-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/4/07; 2/21/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: IDS: 3/16/07; 3/19/07.

DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's amendment filed on January 8, 2007. All previous prior art rejections are maintained. New grounds of rejection are made regarding new claims 21 and 22.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites the limitation "the control parameter" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 9-13 and 15-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ingle (U.S. Pat. No. 6,216,704 B1).

Regarding claim 9, Ingle discloses an ultrasound medical treatment system comprising:

a) an ultrasound medical-treatment transducer 308 (col. 25, ln. 4-10, 52-54 and Figs. 13A-G); and

b) a controller which controls the medical-treatment transducer to emit an ultrasound beam at a first ultrasound acoustic power density to begin to thermally ablate a tissue ablation depth of an area of patient tissue (col. 12, ln. 1-5), wherein the controller reduces the emitted ultrasound beam to a lower second ultrasound acoustic power density based on receiving an indication of an onset in the patient tissue of a transient, ultrasound-caused, ultrasound-attenuating effect to complete the thermal ablation of the tissue ablation depth of the area of the patient tissue without re-aiming the emitted ultrasound beam (col. 25, ln. 42-56).

Regarding the transient, ultrasound-caused, ultrasound-attenuating effect, Ingle discloses monitoring for harmonics or subharmonics of the fundamental carrier ultrasound frequency as an indication of the production of cavitation in the tissue (col. 25, ln. 48-50). On page 5, paragraph 21 of applicant's specification, the applicant discloses that an ultrasound-attenuating effect is caused by tissue cavitation among other things. Therefore, the device of Ingle inherently monitors for and indicates a transient, ultrasound-caused, ultrasound-attenuating effect.

Regarding the reduction of ultrasound power, Ingle discloses adjusting the ultrasound power in response to receiving an indication of an ultrasound-attenuating effect (cavitation) (col. 25, ln. 48-52). At the time the invention was made, it would have been obvious to one of ordinary skill in the art, if not inherent, for the adjustment of the ultrasound power of Ingle to mean a reduction in power in order to eliminate the harmful cavitation effect (col. 24, ln. 50-55).

Regarding claim 10, at the time the invention was made, it would have been obvious to one of ordinary skill in the art, if not inherent, for the device of Ingle to monitor for tissue cavitation in order to reduce the power in order to eliminate the harmful cavitation effect (col. 24, ln. 50-55).

Regarding claim 11, the device of Ingle monitors for cavitation using ultrasound imaging (col. 25, ln. 32-52). Based on applicant's specification (pg. 11, ¶ 33), this cavitation in combination with the ultrasound inherently causes the inception of a proximal hyperechoic region of patient tissue with distal ultrasound attenuation. Thus, the indication of cavitation in the device of Ingle inherently indicates the onset of the ultrasound-attenuating effect as claimed.

Regarding claim 12, see the rejection of claim 9.

Regarding claim 13, see the rejection of claim 9.

Regarding claim 15, see the rejection of claim 9.

Regarding claim 16, see the rejection of claim 11. Ingle discloses using ultrasound to image the treatment area and indicate the occurrence of the ultrasound-

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attenuating effect (col. 25, ln. 32-52), and ultrasound imaging inherently uses ultrasound echoes to form the image.

Regarding claim 17, see the rejection of claim 16. Ingle further discloses that the medical-treatment transducer is an ultrasound medical-imaging-and-treatment transducer, and wherein the imaging ultrasound echo is received by the medical-imaging-and-treatment transducer (col. 25, ln. 32-52)

Regarding claim 18, see the rejection of claim 9.

Regarding claim 19, see the rejection of claim 16.

Regarding claim 20, see the rejections of claims 9-11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ingle ('704) in view of Rolt (U.S. Pat. No. 5,501,655).

Regarding claim 21, see the preceding rejection of claim 9. The claim differs from Ingle in calling for the ultrasound beam to be unfocused or divergent. Rolt, however, teaches using unfocused ultrasound beams as an obvious alternative to focused ultrasound beams (col. 6, ln. 24-28). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used unfocused ultrasound beams in the device of Ingle in view of the teaching of Rolt as an obvious alternate type of ultrasound beam that is well-known in the art and that would have required only routine skill in the art to use.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ingle ('704) in view of Fujimoto (U.S. Pat. No. 5,694,936).

Regarding claim 22, the claim differs from Ingle in calling for control parameter to be the ultrasonic frequency. Fujimoto, however, teaches adjusting ultrasonic frequency in order to suppress cavitation (i.e. a transient, ultrasound-caused, ultrasound-attenuating effect) (Abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used ultrasonic frequency as the control parameter in the device of Ingle in view of the teaching Fujimoto as an obvious alternate way of suppressing cavitation that is known in the art and that would have required only routine skill in the art to perform.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

Regarding claim 9, applicant argues that Ingle does not disclose treatment without re-aiming the ultrasound beam. In support, applicant asserts that Ingle's disclosure of adjusting ultrasound power or scanning speed means that the device necessarily has a non-zero scanning speed.

In response, the examiner first notes that Ingles discloses "adjusting ultrasound power or scanning speed" (col. 25, ln. 48-52). Therefore, the examiner maintains that scanning speed need not even be a factor present and that applicant has improperly assumed that there must a be a non-zero scanning speed. To add further support, Ingle discloses, "It may also be preferable to include at least some axial translation or scanning capabilities for fixed cylindrical symmetrical transducers." (col. 27, ln. 11-14). This indicates that scanning is not necessarily present. Therefore, a device of Ingle without scanning capabilities inherently performs the intended use function of claim 9 as previously set forth in the rejection.

Regarding claim 11, applicant argues that Ingle does not disclose receiving an indication of distal ultrasound attenuation. In response, the examiner maintains that Ingle's receiving an indication of an onset in the patient of a transient, ultrasound-caused, ultrasound-attenuating effect means that the device of Ingle is also inherently receiving a same-time indication of distal ultrasound attenuation because (as stated in the preceding rejection) cavitation in combination with the ultrasound inherently causes the inception of a proximal hyperechoic region of patient tissue with distal ultrasound

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attenuation. Therefore, the indication of the transient, ultrasound-caused, ultrasound-attenuating effect (cavitation) is inherently also an indication of distal ultrasound attenuation. Furthermore, claim 11 consists only of functional descriptive language without any further structure that would define over the device of Ingle.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AT

3/29/07


MICHAEL PEFFLEY
PRIMARY EXAMINER